

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ralph Patrick BRAUN, et al.

PTO9 Rec'd PCT/PTO 17 SEP 2004

Title: Imidazoquinolineamines as Adjuvants in HIV DNA Vaccination

Appl. No.: Unassigned, National Stage of PCT/GB03/01213

Filing Date: September 17, 2004

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

The documents listed on Form PTO/SB/08 were cited by the European Patent Office in the International Search Report for corresponding International Application, PCT/GB03/01213, dated September 29, 2003. Accordingly, copies of the cited documents are not being provided since they should have been provided directly by WIPO under an exchange program between the PTO, the EPO and the JPO.

Further, the U.S.P.T.O. has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statement in a patent application filed after June 30, 2003, and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

The listing of documents on Form PTO/SB/08 came to Applicants' attention during a search of the corresponding International Application, PCT/GB03/01213. A copy of the International Search Report for PCT/GB03/01213 dated September 29, 2003, setting forth the portion of each reference considered relevant by the Examiner is attached.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Information Disclosure Statement
National Stage of PCT/GB03/01213

Atty. Dkt. No. 036481-0157

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date September 17, 2004

By Richard C. Peet

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5483
Facsimile: (202) 672-5399

Richard C. Peet
Attorney for Applicant
Registration No. 35,792

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| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: September 17, 2004 (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | Unassigned, National Stage of PCT/GB03/01213 |
| | | Filing Date | 9/17/2004 10/507928 |
| | | First Named Inventor | Ralph Patrick BRAUN |
| | | Group Art Unit | Unassigned |
| | | Examiner Name | Unassigned |
| | | Attorney Docket Number | 036481-0157 |

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U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| | | Number | Kind Code ² (if known) | | | |
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FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|-------------------------|---------------------|-----------------------------------|--|---|---|----------------|
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | A1 | WIPO | WO 93 20847 | A | MINNESOTA MINING AND MANUFACTURING COMPANY | 10-28-1998 | Claims 1-27 | |
| | A2 | WIPO | WO 01 54719 | A | SMITHKLINE BEECHAM BIOLOGIC. et al. | 08-20-2001 | | |
| | A3 | WIPO | WO 02 24225 | A | GLAXO GROUP LIMITED | 03-28-2002 | Claim 25 | |
| | A4 | WIPO | WO 03 25003 | A | BEATON ANDREW et al. | 03-27-2003 | Claims 1-27 | |
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NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
|--------------------|-----------------------|--|----------------|
| | A5 | BERNSTEIN, et al. "Effect of Imiquimod as an Adjuvant for Immunotherapy of Genital HSV in Guinea-Pigs." <i>Vaccine</i> (1995), vol. 13, no. 1, pp. 72-76. | |
| | A6 | BILLAUT-MULOT, et al. "Modulation of Cellular and Humoral Immune Responses to a Multiepitopic HIV-1 DNA Vaccine by Interleukin-18 DNA Immunization/Viral Protein Boost." <i>Vaccine</i> , April 6, 2001, vol. 19, no. 20-22, pp. 2803-2811. | |
| | A7 | VASILAKOS, et al. "Adjuvant Activities of Immune Response Modifier R-848: Comparison with CPG ODN." <i>Cellular Immunology</i> , August 25, 2000, vol. 204, no. 1, pp. 64-74. | |
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|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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